REMARKS/ARGUMENTS

The specification has been amended to make reference to the priority data. Additionally, the metal ions referenced at page 9 line 6 of the specification and in claim 13 have been amended as suggested by the Examiner.

Claim 38 has been amended to overcome the rejection based upon 35 U.S.C. 101.

To overcome the double patenting rejection of claims 35 and 39 under 35 U.S.C. 101, these claims have been cancelled and claims 34 and 37 have been amended.

Regarding the objection to the definitions for parameters BV, SV and LV, as the Examiner noted, these definitions are recited in the description. Consequently, in response to the Examiner's comments, we have deleted their definition from the claims.

We have also replaced BV_f, SV_f and LV_f with the parameters BV, SV and LV and BV_e, LV_e by BV and LV. The "f" and "e" suffixes are relative to the "fixation" and "elution" steps. However, the claim is quite clear without these suffixes.

Clarifying amendments have also been made to claims 23, 24, 25, 27, 32, 36 and 38 to overcome the issues raised by the Examiner in the Official Action. It is believed that the claims as now presented should be fully compliant with 35 U.S.C. 101 and 112.

Rejection Based on 35 U.S.C. § 102

The amendments to claims 31 and 36 are believed to overcome this ground of rejection.

Rejections Based on 35 U.S.C. § 103

The invention is directed to a method for isolating milk proteins from milk or whey comprising the following steps:

a) sterilizing and defatting;

b) passage over a cation-exchange resin conditioned in an elution column;

c) the retained fraction is eluted with an aqueous salt solution;

d) the eluate resulting from step c) is desalted and sterilized and wherein

α) the cation-exchange resin is a resin grafted onto strong acid functional groups;

β) during step b), the binding parameters have the following values:

- BV is between 50 and 400;
- SV is between 2 and 40 h^{-1};
- LV is greater than or equal to 1 m/h and less than or equal to 5 m/h.

γ) during step c), the elution parameters have the following values:

- BV is between 1.5 and 7;
- LV is less than 1 m/h.

This method makes it possible to obtain a protein fraction with special biological properties. It stimulates the proliferation of osteoblasts, it inhibits the proliferation of pre-osteoclasts and it stimulates the proliferation of Caco-2 cells. This results in improved benefit on bone growth and strength.

Such properties were known for other protein milk fractions with a high lactoferrin content. However, the inventor has demonstrated that in the case of the milk protein fractions of the invention the beneficial effect could not be accounted for by the presence of lactoferrin.

U.S. Patent No. 5,976,597 (Takada et al.), the primary reference relied upon in the obviousness rejection, discloses a basic protein fraction obtained by applying the following steps:

(i) milk is loaded onto a cation exchange resin column,

(ii) elution is performed with an eluent of 0,1-1M salt concentration,

(iii) a precipitate is removed by heating or adding alcohol or adding salts,

(iv) the supernatant is recovered.

No indication is given as to the choice of parameters BV, LV and SV, either at step (i) or step (ii), nor is given any indication that the selection of particular values for those parameters could be of any importance for obtaining the milk protein fractions claimed by applicant. In the examples, the description is insufficient to calculate the value of those parameters (volume of resin, diameter of the column, speed of elution are not indicated).

Moreover, the indications which are given in the description as to the method which should be employed to obtain protein fractions of interest are not detailed in a manner permitting the person skilled in the art to know which steps are essential and which are not.

Reference example 1 (comparative) differs from example 1 in that the method stops after step (ii) and the milk fraction is directly dried without applying steps (iii) and (iv). The same can be said for the other examples.

Consequently, the skilled person understands that steps (iii) and (iv) are not essential for obtaining the protein fractions of interest.

Moreover, the composition disclosed by Takada is a protein composition characterized by a molecular weight distribution and isoelectric points distribution and a proportion of 10% basic amino acids in the protein structure. This definition is clearly different from the proteins of the invention.

U.S. Patent No. 6,010,698 (Kussendrager et al.) is related to a process for recovering growth factors from milk, said process comprising the steps of adsorption on a cation exchanger and elution with a salt solution. Those steps are classical steps of milk protein treatment. The main teaching of this document resides in the further treatment of eluted proteins applying mildly acid conditions.

There are indications of kinetic parameters for the retention and elution steps in this document:

- Col. 3, lines 43-47: indications are insufficient to compare with the parameters claimed in the present application;

- in Example 1, parameters given can be used to calculate the corresponding BV, SV and LV for the retention step, but no indication of such parameters is disclosed for the elution step.

For the retention step BV = 300; LV = 0,5h^{-1}; SV = 10 mh^{-1}. Consequently, LV and SV are clearly outside the claimed range in the present application.

Kussendrager et al. is directed to obtaining fractions rich I angiogenin or peptides deriving from angiogenin, rich in lactoperoxydase and rich in lactoferrin (basic proteins). These fractions are different from those of the present invention.

As for the combination of reference teachings, it should be noted that Takada, like the present invention, is concerned with obtaining a milk protein fraction having improved bone strengthening properties, but Kussendrager aims at fractioning milk growth factors, lactoferrin and lactoperoxydase. The skilled person would have no reason to apply the Kussendrager

improvements to Takada's method, because their aims are different, and because after an elution step they both apply distinct treatment steps. Even if there were some motivation for combining the reference teachings, the person skilled in the art would suppress steps (iii) and (iv) of Takada's method, which are the main improvement brought by Takada to the state of the art. And those steps, which are essential to Takada's teaching, are not used in the method of the present invention.

Moreover, if the skilled person was motivated to combine Takada's teaching with Kussendrager's, he would concentrate on the essence of his teaching, which resides in the mildly acidic conditions applied after elution. And even if he decided, for unpredictable reasons to apply the kinetic parameters used by Kussendrager to Takada's steps (i) and (ii), he would still not obtain the method as defined in the claims of record, because in the retention steps Kussendrager teaches LV and SV out of the range claimed by applicant and because Kussendrager does not give any indication regarding kinetic parameters of the elution steps.

Consequently, the person of ordinary skill in the art, having knowledge of the Takada teachings:

- would not be tempted to combine it with Kussendrager,

- even if he combined both methods in any possible manners, he would not obtain the method claimed in the present application. Accordingly, reconsideration by the Examiner and formal notification of the allowance of all claims as now presented are solicited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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